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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
08/852,666	05/07/97	CHADA	K	UMD-1.0-037C

HM12/1107

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EXAMINER	
SRIVASTAVA,D	
ART UNIT	**PAPER NUMBER**
1653	23

DATE MAILED: 11/07/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary	Application No. 08/852,666	Applicant(s) Chada et al.
	Examiner Devesh Srivastava, Ph.D.	Group Art Unit 1653

☒ Responsive to communication(s) filed on *Sep 28, 2000*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-5, 13-15, 20-22, 26-28, and 33-46* is/are pending in the application.

Of the above, claim(s) *1-5, 13-15, 20-22, 26-28, and 33-40* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *41-46* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Continued Prosecution Application

1. The request filed on September 11, 2000, for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/852,666 is acceptable and a CPA has been established. An action on the CPA follows.

Status of the Claims

2. Applicants' amendment, filed September 28, 2000, has been entered and fully considered. Claims 1-5, 13-15, 20-22, 26-28 and 33-40 remain pending and remain withdrawn from consideration as being drawn to non-elected inventions. Claims 41-46 are newly added. Claims 16-12, 16-19, 23-25 and 29-32, drawn to previously elected subject matter, have been canceled. Currently, claims 41-46, representing newly elected subject matter, are presented for examination.

Objections/Rejections Withdrawn

3. In light of cancellation of all previously pending claims, all previous rejections are withdrawn.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 41-46 are rejected under 35 U.S.C. 112, **second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 41-46 refer to an inhibition of HMGI biological activity, however, the specification does not clearly define biological activity of HMGI proteins. Without a clear definition, it is not possible to understand the metes and bounds of the patent protection desired.

7. Claims 41-46 are rejected under 35 U.S.C. 112, **second paragraph**, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: steps by which binding affinity would be determined and whereby HMGI biological activity is measured and quantified. The method of Claims 41-43 merely determine binding affinity of a candidate compound, which is an unspecified physical measurement, but does not quantify any level of biological activity. The method of Claims 44-46 merely determines levels of reporter gene expression, which indirectly determines the effect of a compound on a promoter.

8. Claim 41, in item (c), line 2, recites the word "whereof", however, it appears the intended term is "thereof". Claims 42-43 are included in this rejection for being dependent on a rejected base claim and not correcting the deficiency of the claim from which they depend.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 41-43 are rejected under 35 U.S.C. 112, **first paragraph**, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the

art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the amount of direction or guidance presented and the amount of experimentation necessary.

The claims are drawn to a method for screening candidate compounds capable of inhibiting HMGI biological activity. The method, in one embodiment, is accomplished using a fragment of a HMGI protein and, in all embodiments, is accomplished by determining a binding affinity for the candidate compound. First, the "fragment thereof" can be broadly interpreted to mean a single amino acid and as such would not accomplish the claimed method since a single amino acid would not be related to HMGI function. Second, determination of a binding affinity, by unspecified means, does not determine which candidate compounds inhibit HMGI biological activity. Third, the claimed method does not teach how a reduction in biological activity would be quantified to meet the limitations of claims 42 and 43. Since it is not routine in the art to engage in *de novo* experimentation where the expectation of success is unpredictable, the skilled artisan would require additional guidance in order to practice the claimed method. Without such guidance, the experimentation left to those skilled in the art is undue.

11. Claims 44-46 are rejected under 35 U.S.C. 112, **first paragraph**, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the

art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the amount of direction or guidance presented and the amount of experimentation necessary.

The claims are drawn to a method for screening candidate compounds capable of inhibiting HMGI biological activity. The method is accomplished using a host cell comprising a reporter gene under control of an HMGI protein-regulated promoter in the presence of a candidate compound. First, the specification does not teach any HMGI protein-regulated promoter and therefore the skilled artisan would not know with what material to begin the assay. Second, determination of a reporter gene expression, by unspecified means, does not determine which candidate compounds inhibit HMGI biological activity. Third, the claimed method does not teach how a reduction in biological activity would be quantified to meet the limitations of claims 45 and 46. Since it is not routine in the art to engage in *de novo* experimentation where the expectation of success is unpredictable, the skilled artisan would require additional guidance in order to practice the claimed method. Without such guidance, the experimentation left to those skilled in the art is undue.

12. Claims 44-46 are rejected under 35 U.S.C. 112, **first paragraph**, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed method recites a step whereby a cell is transfected with "a DNA construct which contains a reporter gene under control of an HMGI protein-regulated promoter". The specification does not disclose any HMGI protein-regulated promoter. The courts have ruled that a description of the DNA is required to adequately describe the claimed invention.

> "An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, 'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel,* 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, '**an adequate written description of a DNA requires more than a mere statement that it is a part of the invention** and reference to a potential method for isolating it; **what is required is a description of the DNA itself.**' Id. at 1170, 25 USPQ2d at 1606." *University of California v. Eli Lilly and Co.* (CAFC) 43 USPQ2d 1398 (1997). (Emphasis added)

Given this lack of adequate written description, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would not recognize Applicants were in possession of the claimed invention.

Conclusion

13. Claims 1-5, 13-15, 20-22, 26-28 and 33-40 are withdrawn from consideration as being drawn to non-elected inventions.

14. Claims 41-46 are rejected.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Devesh Srivastava, Ph.D. whose telephone number is (703) 305-0775. The examiner can normally be reached on Monday-Thursday from 8:00 am to 5:30 pm and alternate Fridays from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph.D., can be reached on (703) 308-2923. The FAX phone number for the Art Unit where this application or proceeding is assigned is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Devesh Srivastava, Ph.D.
Patent Examiner
November 3, 2000

Christopher S. F. Low

CHRISTOPHER S. F. LOW
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